K061113

AXON SYSTEMS

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510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

Summary Date:	April 14, 2006
Submitter's Information:	Howard Bailin Vice President, C.O.O. Axon Systems, Inc. 400-2200 Oser Ave Hauppauge, NY 11788 P: 631 436 5112 F: 631 436 5141 hbailin@axonsystems.com
Trade Name:	OrthoMon
Common Name:	EMG monitor, Evoked Potential System
Classification Name:	Evoked Response, Electromyograph
Classification:	Number: 882.1870 Electromyograph Monitor, Surgical Nerve Stimulator/Locator, Diagnostic Electromyograph, Evoked Response Stimulator
Product Codes:	GWF, IKN
Predicate Devices	Axon Systems: Eclipse Neurological Workstation (K050798) NuVasive: Neurovision JJB (K051384) Datex-Ohmeda: M-NMT Neuromuscular Transmission Module (K955026)

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Description:

The Orthomon system provides continuous, 8 channel, monitoring of neural motor pathways intraoperatively and is used to locate and assess spinal nerves, verify placement of orthopedic instrumentation in order to reduce the risk of nerve root injury and to access spinal cord motor function.

The system performs these functions automatically or manually and uses several neurophysiological techniques including: free run and stimulus evoked electromyography (EMG), transcranial electrical motor evoked potentials and train of four.

The main OrthoMon system components include: the console, housing the computer, controller and sensory and motor evoked potential electrical stimulator and patient module located at the OR table to route stimuli to the appropriate sites and electrode preamplifier harness. The electrode harnesses contains 8 recording sites. Each site connects to a quick-apply disposable surface electrode.

A pre-sterilized, disposable, hand-held, microprocessor controlled probe operated by the surgeon, connects to the patient module. The probe directs stimulation to the appropriate site, controls certain test functions and settings and provide visual indication of test results.

The OrthoMon interface is a touch screen with optional keyboard and mouse. A built-in speaker may be used for audible EMG or signal trigger tones.

The system is network compatible for data review within the hospital and permits secure information access over the Internet.

Technologically, OrthoMon is similar to the predicate devices. The exceptions are the use of a surgeon controlled probe to select certain test functions and to direct the stimulation; and use of quick-apply disposable surface electrodes.

OrthoMon was tested functionally using accepted laboratory test procedures.

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Intended Use: The OrthMon system is intended for use to record, monitor and stimulate/record biopotential signals including electromyograph (EMG), evoked response and nerve/muscle potentials and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction.

The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at risk nerve roots.

Conclusions: Based on the technical information provided in this 510(k) and the safety and effectiveness criteria of the design and development process, validated and verified, we claim the OrthoMon to be safe, effective and substantially equivalent to the predicate device(s) noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2006

Axon Systems
C/o Mr. Howard Bailin
Vice President, C.O.O,
400- 2200 Oser Avenue,
Hauppauge, NY 11788.

Re: K061113
Trade Name: Orthomon System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Stimulator
Regulatory Class: II
Product Code: GWF, IKN
Dated: April 14, 2006
Received: April 21, 2006

Dear Mr. Bailin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number K061113

Device Name **OrthoMon**

Indications for Use

The OrthMon system is intended for use to record, monitor and stimulate/record biopotential signals including electromyograph (EMG), evoked response and nerve/muscle potentials and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction.

The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at risk nerve roots.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)